

Claim 9 was first objected to due to an informality pointed out by the Examiner. Applicant has amended the claim 9 in accordance with the Examiner's suggestions as set out in the above amendment in order to overcome the Examiner's objection.

35 U.S.C. §112 Rejections

The Examiner rejected claims 9-12 under 35 U.S.C. section 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter of the invention. Specific instances are set out by the examiner at pages 2-3 of the Examiner's Office Action. In response to the Examiner's rejection, Applicants' have amended claims 9-12 to more specifically claim the subject matter of Applicants' invention.

35 U.S.C. §102(a) Rejections

Claims 9 and 11 stand rejected under 35 U.S.C. §102(a) as being anticipated by *Bieber et al.* (Mass Spectrometric Immunoassay, Analytical Chemistry 1995, 67, 1153-1158), (hereinafter "Bieber"). Applicants respectfully traverse this rejection.

Under 35 U.S.C. Sec. 102(a), a person is entitled to a patent unless the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent. The *Bieber* journal article cited by the Examiner does not constitute a description of the invention in a printed publication before the invention was made by Applicants in that at least one of the Applicants is an author of the journal article and conceived the broadest claim of the invention before the publication of the journal article. Accordingly, Claims 9-12 are not anticipated by *Bieber* and Applicants respectfully request the withdrawal of the Examiner's rejection under 35 U.S.C. Sec. 102(a).

35 U.S.C. §103(a) Rejections

Claims 10 and 12 stand rejected under 35 U.S.C. §103(a) as being unpatentable over *Bieber* in view of *Ogura et al.*, U.K. Patent No. 2,030,294 (hereinafter "Ogura"). Applicants respectfully traverse this rejection.

As previously pointed out above with reference to the Examiner's 35 U.S.C. Sec. 102(a)

rejection, the *Bieber* reference does not constitute prior art for purposes of the Examiner's 35 U.S.C. Sec. 103(a) rejections because the *Bieber* publication was authored by at least one of the inventors that conceived the broadest claim of the invention prior to the publication. Accordingly, if the *Bieber* reference is removed from the Examiner's 35 U.S.C. Sec. 103(a) rejections, it would clearly not have been obvious to one of ordinary skill in the art to arrive at the Applicants' claimed invention. Therefore, Applicants respectfully request the withdrawal of the Examiner's 35 U.S.C. Sec. 103(a) rejections.

In view of the foregoing, Applicants respectfully submit that all of the pending claims fully comply with 35 U.S.C. §112 and are allowable over the prior art of record. Reconsideration of the application and allowance of all pending claims is earnestly solicited. Should the Examiner wish to discuss any of the above in greater detail, or deem that further amendments should be made to improve the form of the claims, then the Examiner is invited to telephone the undersigned at the Examiner's convenience.

Attached hereto is a marked-up version of the changes made to the specification and claims by the current Amendment. The attached page is captioned "VERSION WITH MARKINGS TO SHOW CHANGES MADE".

Respectfully submitted,

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VERSION WITH MARKINGS TO SHOW CHANGES MADEIn the Claims:

The claims have been amended as follows:

--9. (AMENDED) A method for isolation and subsequent qualitative characterization of target biomolecules present in a biological fluid comprising the steps of:

- a. providing a [MSIA-Tip] pipettor tip having an affinity reagent present;
- b. separating and [concentration] concentrating the target biomolecule directly from the biological fluid by flowing a volume of the biological fluid through the [MSIA-Tip] pipettor tip, thereby binding the target biomolecules to the affinity reagent;
- c. eluting the target biomolecules onto a mass spectrometer target; and
- d. performing mass spectrometric analysis on the target biomolecules in order to qualitatively determine the presence or absence of the target biomolecule in the biological fluid.—

--11. (AMENDED) The method according to claim 9 wherein the qualitative determination further determines [the] a presence of [mass shifted] genetic and posttranslational variants of the target biomolecule.—

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--12. (AMENDED) The method according to claim 10 wherein the qualitative determination further determines [the] a presence of [mass shifted] genetic and posttranslational variants of the target biomolecule--.

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